JAN 2 8 2002

Wiener lab.
Especialidades para Laboratorios Clínicos
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Section 6 – Summary

510(k) Summary
"This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21CFR 807.92"

"The assigned 510(k) number is: K013983 **"**

Introduction

According to the requirements of 21 CFR 862.1050, the following information provides sufficient details to understand the basis of a determination of substantial equivalence.

6-1 Submitter Name, Address, Contact

Wiener Laboratorios S.A.I.C.
Riobamba 2944
2000 – Rosario - Argentina

Contact person: Viviana Cétola
Date Prepared: February 23, 2001

6-2 Device Name

Proprietary name:	WIENER LAB. ALP 405
Common name:	Alkaline phosphatase test system.
Classification name:	Nitrophenylphosphate, Alkaline Phosphatase or Isoenzymes

Device Class II

6-3 Predicate Device

We claim substantial equivalence to the currently marketed RANDOX ALKALINE PHOSPHATASE OPT. test system (Cat. Nº AP307).

6-4 Device Description

Alkaline phosphatase (ALP or orthophosphoric monoester phosphohydrolase - EC 3.1.3.1.) hydrolyzes colorless paranitrophenyl phosphate (pNPP) producing phosphate and p-nitrophenol at pH 9.8. The speed at which the p-nitrophenolate anion (yellow) appears, read at 405 nm, is directly proportional to the enzymatic activity of the sample.

6-5 Intended Use

The ALP 405 test system is intended to be used in the quantitative determination of alkaline phosphatase in human serum and heparinized plasmas. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

6-6 Equivalencies and Differences

The WIENER LAB. ALP 405 test system is substantially equivalent to other products in commercial distribution intended for similar use. Most notably it is substantially equivalent to the currently marketed RANDOX ALKALINE PHOSPHATASE OPT test system.

The following table illustrates the similarities and differences between the WIENER LAB. ALP 405 test system and the currently marketed RANDOX ALKALINE PHOSPHATASE OPT test system.

	RANDOX Test System	WIENER LAB. Test System
Intended use	Quantitative determination of alkaline phosphatase in human serum and heparinized plasma.	
Test principle	Alkaline phosphatase (ALP or orthophosphoric monoester phosphohydrolase - EC 3.1.3.1.) hydrolyzes colorless paranitrophenyl phosphate (pNPP) producing phosphate and p-nitrophenol at pH 9.8. The speed at which the p-nitrophenolate anion (yellow) appears, read at 405 nm, is directly proportional to the enzymatic activity of the sample.	
Essential Components	p-Nitrophenylphosphate (p-NPP) - DEA	
Reagents	R1: p-NPP R2: Buffer	R1: p-NPP R2: Buffer
Instability or deterioration of reagents	Not specified	Reagent Blank Absorbance > 0.900
Sample	Human serum and heparinized plasma	
Working Temperatures	25 - 30 - 37°C	
Wavelength of reading.	405 nm	
Linearity	825 U/l	1,400 U/l
Minimum detection limit	Not specified	8.7 U/l

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	RANDOX Test System	WIENER LAB. Test System
Expected values	Adults: 98 - 279 U/l (37°C)	Adults: 65 - 300 U/l (37°C) Children: until 645 (37°C)
Within-run precision	No stated in insert.	Normal Serum Control: CV = 2.2% Abnormal Serum Control: CV = 0.7%
Total precision	No stated in insert.	Normal Serum Control: CV = 2.4% Abnormal Serum Control: CV = 0.9%

6-7 Conclusion Based on the data above mentioned, we believe that the extended claims continue to support substantial equivalence to other products in commercial distribution intended for similar use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

JAN 2 8 2002

Dr, Vivianna Cetola
QC/QA Manager
Weiner Laboratorios S.A.I.C.
Riobamba 2944,
Rosairo 2000
Santa Fe
Argentina

Re: k013983
Trade/Device Name: Weiner Lab. ALP 405
Regulation Number: 21 CFR 862.1050
Regulation Name: Alkaline phosphatase or isoenzymes test system
Regulatory Class: Class II
Product Code: CJE
Dated: November 14, 2001
Received: December 3, 2001

Dear Dr. Cetola:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K013983

510(k) Number (if known): K013983

Device Name: Wiener lab.
ALP 405

Indications For Use:

The "Wiener lab. ALP 405" test system is an in vitro diagnostic device intended to be used in the quantitative determination of alkaline phosphatase in human serum and heparinized plasmas. Measurements of alkaline phosphatase or its isoenzymes are used in the diagnosis and treatment of liver, bone, parathyroid, and intestinal diseases.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Carol C Benson for Jean Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K013983

Prescription Use ✓
(Per 21 CFR 801.109)

OR

Over-The-Counter Use ___

(Optional Format 1-2-96)

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